

January 1, 1998

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Center: _____

Patient Initials: _____, _____

Rand Number: _____

Form
completed by: _____**A copy of this form should be faxed to the SCC at (301) 881-5928 by the next working day.****A. VERIFICATION OF INCLUSION CRITERIA** (*all answers must be YES*)1. Postmenopausal? **deleted**Y₁ N₃2. Qualifying angiogram within previous 4 months? **deleted**Y₁ N₃3. Signed informed consent? **deleted**Y₁ N₃**B. VERIFICATION OF EXCLUSION CRITERIA** (*all answers must be NO*)1. Creatinine >2.0 mg/dL (>177 µmol/L)? **deleted**Y₁ N₃2. Unwilling to stop concurrent hormone replacement therapy? **deleted**Y₁ N₃

3. Unwilling to stop vitamin C (>60 mg/day) and/or E (>30 IU/day) supplements?

Y₁ N₃**deleted**4. Planned or prior coronary artery bypass grafting? **deleted**Y₁ N₃5. NYHA class IV heart failure or known ejection fraction <25%? **deleted**Y₁ N₃6. MI less than 4 weeks prior to randomization? **deleted**Y₁ N₃7. Concurrent participation in another blinded clinical trial? **deleted**Y₁ N₃8. Symptomatic gallstones? **deleted**Y₁ N₃9. History of PE or idiopathic DVT? **deleted**Y₁ N₃10. History of hemorrhagic stroke or bleeding diathesis? **deleted**Y₁ N₃11. Breast cancer or mammogram suggestive of cancer? **deleted**Y₁ N₃12. Known endometrial hyperplasia or abnormal uterine bleeding? **deleted**Y₁ N₃13. History of endometrial carcinoma without hysterectomy? **deleted**Y₁ N₃14. Abnormal Pap smear with dysplasia of grade CIN-I or greater? **deleted**Y₁ N₃15. Documented fasting triglycerides >500mg/dL (>5.65 mmol/L)? **deleted**Y₁ N₃16. Uncontrolled diabetes mellitus? **deleted**Y₁ N₃17. Uncontrolled hypertension? **deleted**Y₁ N₃18. Anticipated survival <3 years? **deleted**Y₁ N₃19. Unlikely to adhere to protocol in the opinion of the investigator? **deleted**Y₁ N₃20. Angiogram not meeting protocol criteria? **deleted**Y₁ N₃21. History of osteoporosis, either untreated or currently treated with HRT? **deleted**Y₁ N₃**ELIG = eligibility criteria satisfied (1=yes; 0=no)**

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C. PHYSICAL MEASURES AT RANDOMIZATION

1. Blood pressure (mmHg):
- C_SBP = systolic / C_DBP = diastolic**

____ / ____
Systolic Diastolic

2. Height:
- C_HCCM**

____ . ____ cm OR ____ ft ____ . ____ in

3. Weight:
- C_WTKG**

____ . ____ kg OR ____ lb ____ . ____ oz

4. Waist circumference:
- C_WCCM**

____ . ____ cm OR ____ . ____ in

5. Hip circumference:
- C_HCCM**

____ . ____ cm OR ____ . ____ in

D. RANDOMIZATION PROCEDURE CHECKLIST

1. Fasting study bloods drawn?
- C_FBL**

Y₁ N₃

- a. If Yes, date of samples:
- deleted**

____ / ____ / ____
Month Day Year**Replaced with C_FBLDY = # of days between randomization and blood draw**

2. Study angiogram done?
- C_SANG**

Y₁ N₃

- a. If Yes, date of angiogram:
- deleted**

____ / ____ / ____
Month Day Year**Replaced by C_SANGDY = # of days between randomization and entry angiogram**

3. ECG done?
- C_ECG**

Y₁ N₃

- a. If Yes, date of ECG:
- deleted**

____ / ____ / ____
Month Day Year**Replaced by C_ECGDY = # of days between randomization and entry ECG**

E. RANDOMIZATION

1. Patient's screening ID number: **deleted**

2. Did the patient have a hysterectomy? **C_HYST**

3. Bottle code of HRT study medication dispensed: **deleted**

Replaced by C_HRTDP =HRT dispensed (0=no; 1=yes)

4. Bottle code of Vitamin C study medication dispensed **deleted**

Replaced by C_VITCDP =Vitamin C dispensed (0=no; 1=yes)

5. Bottle code of Vitamin E study medication dispensed: : **deleted**

Replaced by C_VITEDP =Vitamin E dispensed (0=no; 1=yes)

6. Open label multi-vitamin dispensed? **C_MULTI**

7. Date of randomization: **deleted**

— — — —

Y₁ N₃

— - — —

C - — —

E - — —

Y₁ N₃

— — / — — / — —
Month Day Year